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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/823,176

04/13/2004

Jay A. Dittman

8627/219

3747

48004

7590

02/12/2009

BRINKS HOFER GILSON & LIONE/INDY/COOK  
ONE INDIANA SQUARE  
SUITE 1600  
INDIANAPOLIS, IN 46204-2033

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

02/12/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/823,176	<b>Applicant(s)</b> DITTMAN ET AL.	
	<b>Examiner</b> CHRISTOPHER D. KOHARSKI	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 22-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/19/04, 8/6/04, 8/30/04</u> .                                | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 21-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group (group I selected), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/18/2008.

### ***Acknowledgements***

The Examiner acknowledges the reply filed 11/18/2008 in which no claims were amended. Currently claims 1-28 are pending for examination in this application with claims 21-28 withdrawn from a previous election restriction.

### ***Information Disclosure Statement***

The information disclosure statements (IDS) that were submitted on 07/19/2004, 08/06/2004, 08/30/2004 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statements.

### ***Specification***

The abstract of the disclosure is objected to because claimed subject matter is not present within the specification. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: Regarding the claim scope of claims 3-4 and 7, these ranges lack antecedent basis within the specification. Several French diameters/ranges are disclosed; however the specific ranges as claimed are not described in the specification.

Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 10, 14-15, and 20-21 are rejected under 35 U.S.C 103(a) as being unpatentable over Parker (USPN5,700,253) in view of Lepulu et al. (USPN6,533,770).

Regarding claims 1-6, 10, 14-15, and 20-21, Parker et al. discloses an introducer sheath (Figure 3), comprising: an PTFE inner tube (46) having a passageway extending longitudinally therethrough, said passageway having a substantially uniform diameter; a coil (48) made of flat ribbon having a plurality of coil turns extending longitudinally around said inner tube (46), and a plurality of predetermined spacing's between said turns; and a nylon outer tube (44) positioned longitudinally around said coil (48) and said inner tube (46) connected to inner tube through the spacing's between said turns, wherein said spacing's between said coil turns have a uniform width; a radiographic

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marker tube (72) comprises polyamide and is disposed along said sheath between said inner tube (46) and said outer tube (44) (Figures 1-5).

Parker meets the claim limitations as described above except for the introducer sheath diameter and side hole.

However, Lepulu et al. teaches a cannula and method of manufacture.

Regarding claims 1-6, 10, 14-15, and 20-21, Lepulu et al. teaches discloses an introducer sheath (Figure 22), comprising: a tube (372) having a passageway extending longitudinally therethrough ranging from a diameter of 19-32 French (col 18, ln 50-60), said passageway having a substantially uniform diameter; a side port (390) located in the sheath wall (Figure 22).

At the time of the invention, it would have been obvious to construct the device of Parker to the size as taught by Lepulu et al. because it is well known in the medical arts to adjust the size medical devices to different patients and procedures. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Lepulu et al. (cols 1-2). Additionally, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See, *In re Aller*, 105 USPQ 233 (CCPA 1955).

***Claim Rejections - 35 USC § 103***

Claims 7-9, 11, and 13 are rejected under 35 U.S.C 103(a) as being unpatentable over Parker (USPN5,700,253) in view of Lepulu et al. (USPN6,533,770) in further view of Parker (USPN5,769,830). The modified Parker meets the claim limitations as described above except for the claimed Shore D hardness and radioopaque densities.

However, Parker teaches a guiding catheter.

Regarding claims 7-9, 11 and 13, Parker teaches discloses an introducer sheath (Figures 1-2), comprising: a tube (10) with a varied Shore D hardness from 50-65 (col 4, ln 1-20, 40-50) having a passageway extending longitudinally therethrough, said passageway having a substantially uniform diameter; a coil (26) located in the sheath wall, a radioopaque marker (27, 34) with varied weight percents from 10-90% filler (col 4, ln 60-67, col 5, ln 1-40).

At the time of the invention, it would have been obvious to construct the invention of the modified Parker with the properties as disclosed by Parker ('830) because it is well known in the art to vary the radioopaque properties to enhance visibility within the body and to vary the material hardness to optimize insertion and tracking within the body. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Parker (cols 1-2). Additionally, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See, *In re Aller*, 105 USPQ 233 (CCPA 1955).

***Claim Rejections - 35 USC § 103***

Claims 16-19 are rejected under 35 U.S.C 103(a) as being unpatentable over Parker (USPN5,700,253) in view of Lepulu et al. (USPN6,533,770).

Regarding claims 16-19, the modified Parker discloses the claimed invention except for specific wire coil sizes and spacing. Lacking specific criticality, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the modified device of Parker with the metal coil measurements as claimed because it is well known in the art to vary the coil size, spacing, and length in order to adjust the stiffness of the sheath in order to promote insertion without kinking and enhance tracking within the patient, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See *In re Aller*, 105 USPQ 233 (CCPA 1955).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 02/05/2009

/Christopher D Koharski/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763